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RECORD OF ORAL HEARING

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex Parte SALUH KIVLIGHN, RICHARD JOHNSON,
and MURILDA MASSALI

Appeal 2009-005057
Application 09/892,505
Technology Center 1600

Oral Hearing Held: January 7, 2010

Before DONALD E. ADAMS, LORA M. GREEN, and
RICHARD M. LEBOVITZ, *Administrative Patent Judges.*

APPEARANCES:

ON BEHALF OF THE APPELLANT:

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The above-entitled matter came on for hearing Thursday, January 7, 2010, commencing at the U.S. Patent and Trademark Office, 600 Dulany Street, Alexandria, Virginia, before Victor Lindsay, a Notary Public.

THE USHER: Calendar No. 5, Appeal No. 2009-5057, Mr. Van Dyke.

JUDGE ADAMS: Good morning, Mr. Van Dyke.

MR. VAN DYKE: Good morning.

JUDGE ADAMS: We're familiar with the case, and you'll have 20 minutes, and if you would begin either by presenting your business card or spelling your name into the record for our court reporter.

MR. VAN DYKE: Sure. I don't think I have one handy, so let me spell it.

JUDGE ADAMS: If you wouldn't mind introducing your colleagues, we'd appreciate it.

MR. VAN DYKE: Yes. Well, my name is Timothy Van Dyke, V A N D Y K E. Would you like to know the law firm?

JUDGE ADAMS: I don't think that's necessary.

MR. VAN DYKE: Okay. And I have with me Dr. Richard Johnson.

MR. JOHNSON: Right here.

JUDGE ADAMS: Greetings.

MR. VAN DYKE: And --

UNKNOWN SPEAKER: I'm just a member of the public observing.

JUDGE ADAMS: Oh, okay.

MR. VAN DYKE: -- member of the public observing.

JUDGE ADAMS: Thank you.

MR. VAN DYKE: Okay. Can we begin?

JUDGE ADAMS: Please.

MR. VAN DYKE: Okay, thank you. Well, may it please the Board, I've just introduced myself and I represent the Appellants in this case. There are three pending rejections -- I mean, sorry, three pending claims, Claims 16, 17, and 18, and there are two rejections at issue. The first rejections are rejections to Claims 16 and 17 as being obvious over the Maeda Patent in view of the European Nakamoto Patent and also in view of Applicant's remarks. The second rejection is the rejection of Claim 18 which is rejected in view of the first and second Baldwin Patents.

So I'd like to begin with the first rejection of Claims 16 and 17. It is the Appellants' position that this rejection is made in error, and we ask that the Board reverse the rejection for the following reasons. Beginning with the primary Maeda Patent, the Maeda Patent does not teach/suggest that uric acid is causative of hypertension, and the Examiner even acknowledges that the Maeda Patent does not teach the administration of xanthine oxidase inhibitor in order to lower uric acid to specified levels so that -- as a treatment for hypertension.

JUDGE GREEN: Why does the reference have to teach that uric acid is causative? I mean the reference teaches the administration of xanthine oxidase inhibitor, it teaches that to treat hypertension, and it teaches that these inhibitors also reduce uric acid levels. Why wouldn't that meet everything in your Claim 16?

MR. VAN DYKE: Well, in Claim 16, we have -- one of the discoveries here is that there are -- there is a spectrum of uric acid levels and

what that -- that humans have, and what we have found are -- I'm sorry, the inventors have found is that these levels need to be lowered to a certain degree. And --

JUDGE GREEN: So are you saying that that's a positive method step or is that just something that's inherent to the treatment of hypertension?

MR. VAN DYKE: It's a positive method step, I think.

JUDGE GREEN: That you have to go in and measure levels of uric acid?

MR. VAN DYKE: No, I'm sorry, no, not to measure them, but a dosage has to be -- I mean the administration of the xanthine oxidase inhibitor would have to achieve those levels.

JUDGE GREEN: But if you're administering xanthine oxidase inhibitor and you're treating hypertension, wouldn't that be inherent in that method that in most patients you're going to get this type of uric acid level?

MR. VAN DYKE: Well --

JUDGE GREEN: I mean, otherwise it's -- I mean, all the pieces are there in Maeda as to Claim 16. I'm just curious why this would be so unexpected or why you wouldn't inherently get it if you treat hypertension using the xathine oxidase inhibitors in Maeda?

MR. VAN DYKE: Well, I think we can agree that the Maeda Patent does not teach that uric acid should be targeted. I mean, I think we can agree on that point. And -- but I understand what you're saying, that there would be inherency. The Examiner didn't view that as an issue and thought that there was a necessity to bring in other prior art in order to establish that.

JUDGE GREEN: Well, he kind of brought in Nakamoto also to reach limitation of Claim 17 which was the -- I'm going to pronounce incorrectly, and I apologize, but the Alopurine --

MR. VAN DYKE: Allopurinol.

JUDGE GREEN: Allopurinol.

MR. VAN DYKE: Allopurinol, yes. Well, I think there's two other things that I would like for you to consider. One of them is that the Maeda Patent focuses on specific mechanism by which the xanthine oxidase inhibitors --

JUDGE GREEN: I understand all of that, but why wouldn't you inherently get these uric acid levels if you're treating a patient with the xanthine oxidase inhibitor Maeda?

MR. VAN DYKE: Well, we don't know actually if you would or not. And we -- the Appellant submitted expert opinion testimony from Dr. Rodriguez-Iturbe where he said that he's done work in the spontaneous hypertensive rat which is the same rat model that was used in Maeda. And there was a short-term effect that it's recognized that this model -- that treating this model with a xanthine oxidase inhibitor does not have a long-term effect, and, as a matter of fact, treating with a xanthine oxidase inhibitor in this model does not, does not differentiate the uric acid levels in that model versus the control. And so, what's happening is that -- I think what the facts are saying is that there are a couple of modes that a xanthine oxidase inhibitor may exert its effect. One of them would be through the generation of -- I'm sorry, the xanthine oxidase inhibitor would generate oxidants, and if you can lower oxidant level, there's, there's a quadrant or a

portion of the hypertensive effect that's a result of the oxidant level. And there is also another effect of hypertension that is due to uric acid levels, and, in fact, the administration of xanthine oxidase has to be dosed differently and longer in order to lower uric acids to a level where you would see a beneficial effect of hypertension versus a much more rapid exhibition of lowering oxidants.

JUDGE GREEN: And all of that's in the Declaration?

MR. VAN DYKE: Well, there are two -- the main Declaration that I think touches on this point is the Declaration of Dr. Rodriguez-Iturbe, and he has discussed this phenomenon regarding the spontaneous hypertensive rat that is used in Maeda. Note that Maeda shows no data in any other model. And he also recognizes that it is known in the prior art -- it's known in the art that ultimately these studies of xanthine oxidase inhibitors in this model did not, did not pan out as demonstrated that they could lower hypertension. Those two points are definitely in the Declaration.

JUDGE GREEN: But there's nothing about the different dosing or anything else?

MR. VAN DYKE: No, not about the different dosing.

JUDGE GREEN: Because that goes back to the inherency. I mean if you could say well, you have to do different dosing regimen and everything else, but if I have no evidence of that in the record, I can't go there, right?

MR. VAN DYKE: Well, I, I think that there may not be direct evidence. I think that there is circumstantial evidence that's supported by both of these phenomena I've just discussed. I understand your point regarding inherency and I -- that was a point that I thought we were sort of

beyond in the record and wasn't really an issue that was raised in the last Office Action.

JUDGE GREEN: Has it ever been raised?

MR. VAN DYKE: No, not to my recollection. I'm not --

JUDGE GREEN: So you're not beyond inherency, you've never explored inherency?

MR. VAN DYKE: Well, I figured this prosecution's been going on for nearly eight years, it would have reared its head at this point, by this time, but it hasn't been something that we've addressed.

JUDGE GREEN: Okay.

MR. VAN DYKE: I think the Maeda Patent actually was -- well, it's been cited off and on. I can't recall exactly the first time that it was cited.

JUDGE GREEN: But your Claim 16 is fairly broad because it reads on any xanthine oxidase inhibitor.

MR. VAN DYKE: It is -- it does, it does. And I think that if I could also just point out with respect to Claim 17 on this point --

JUDGE GREEN: Which you didn't argue separately.

MR. VAN DYKE: Which we didn't argue separately.

JUDGE ADAMS: Right, so we're just going to focus on Claim 16.

MR. VAN DYKE: Okay, and we have -- I'll sub Claim 18. Well, I'd like to maybe just quickly talk about the other secondary references that are cited. I understand the, the point regarding the Maeda Patent, but I would like to at least raise this issue regarding Nakamoto. It is our position that the Nakamoto reference is actually directed to a new compound for treating gout, and there's one statement in that reference that the Examiner cites to as

supporting this idea that uric acid should be targeted as a treatment of hypertension. And I don't know if you're familiar with the statement, I would like to at least state it for the record. The Nakamoto Patent states that the compound on this invention is effective in curing gout by ameliorating and curing hyperuricemia. This disease often accompanies hypertension, arterial sclerosis, and myocardial infarction because of characteristics of the disease. Accordingly, the compound of the present invention is effective in curing or preventing hypertension, arterial sclerosis, or myocardial infarction accompanied by hyperuricemia.

It is our position that this statement is flawed on its face. It's making the classic mistake of equating association with causation. We provided different examples in the record. Just to reiterate quickly, we, we had the one somewhat absurd example of saying that beer drinking is associated with Super Bowl watching and so, therefore, watching the Super Bowl causes beer drinking is essentially analogous to what the statement is saying. It's saying that gout is accompanied by hypertension, so if something cures gout, then it should cure hypertension. And our position is that under any thinking in the art and science that this, this difference between correlation and causation needs to be noted, and this statement completely disregards that.

We -- I also point out that we have Appellant -- I mean, I'm sorry, we have expert opinion on this issue, and I'd like to quickly quote the statement of Dr. Weir when he -- and his interpretation of this statement made in Nakamoto. The Nakamoto reference is flawed from a medical scientific perspective that even a person of little skill in the art would discount it

outright, especially since Nakamoto provides zero supporting date of evidence that uric acid is a cause of hypertension. Consistent with this point, a lit serach and PubMed and patent search of the USPTO data base using the authors' names identified no citations to their worth. So we point this out that this expert agrees with our interpretation of this statement and also that it would be given no weight. So it could not be pointed to as, as teaching one skilled in the art that uric acid should be targeted as a treatment of hypertension.

And, and lastly on this rejection, the Examiner has cited two of Applicants' own remarks, we believe that this is misguided and that the remarks are mischaracterized. Nowhere can the Examiner point to remarks where the Applicants have admitted that it was known in the art that uric acid was causative of hypertension. The Applicants have acknowledged that it is known that uric acid has been associated with hypertension or as a possible risk factor, but as I already pointed out, having an association is much different than causation. And really it's the discovery that uric acid is causative of hypertension that is the crux of this invention which led to the methods of specifically targeting uric acid to treat hypertension.

JUDGE ADAMS: I realize we've been asking a number of questions, but we're running into a little bit of a time constraint.

MR. VAN DYKE: Okay.

JUDGE ADAMS: If you could wrap up your comments with regard to this rejection and move on to the next rejection, we'd appreciate it.

MR. VAN DYKE: Thank you. Yes, just quickly in conclusion on the first rejection is that it is Appellants' position that this rejection is made in

error, that the -- all the elements of the claims, 16, 17, are not taught in the prior art and that Appellants have provided evidence that there would have been no reasonable expectation in the art that you could treat hypertension by controlling uric acid levels.

Moving to the second rejection, this is the rejection of Claim 18 which pertains to the treatment of hypertension by administering therapeutic amount of Allopurinol. This Claim 18 is rejected in, in view -- as this being obvious over the first and second Baldwin references. I point out that nowhere do either of these Baldwin references teach that uric acid levels are causally related to hypertension, this is a central point that we've made before. And nowhere do they recognize or teach that inhibiting xanthine oxidase will -- is mechanistic for lowering hypertension.

JUDGE LEBOVITZ: Do they teach Allopurinol?

MR. VAN DYKE: They do not teach Allopurinol as doing anything other than recognizing what it was known for, and that is it's a known xanthine oxidase inhibitor.

JUDGE LEBOVITZ: What did they teach that it was used for? Did they teach it for treating hypertension?

MR. VAN DYKE: No, they did not teach that it was for treating hypertension, for gout.

JUDGE LEBOVITZ: For gout?

MR. VAN DYKE: Yes. And so without having a recognition that it's the uric acid that's causative, I don't think it's fair to say that you have -- just because these other compounds have certain properties, there is not

connection of why you would use a totally unrelated compound for a certain purpose.

JUDGE LEBOVITZ: So where did the Examiner get the hypertension teaching from?

MR. VAN DYKE: Well, what the -- the Baldwin references are very limited in reference to Allopurinol. I mean I think that, that they are used -- that the Examiner is just using a statement in the background of the -- one of the Patents as recognizing Allopurinol as a known xanthine oxidase inhibitor. I mean it's used for gout treatment. And so what the Examiner is saying is well, there are these other groups of compounds that can -- that we are showing have xanthine oxidase inhibitor activity and some that show hypertensive activity. And so -- and our position is that she's making a leap from that to saying well, here's this other compound that's a known xanthine oxidase inhibitor, so it must be able to teach -- to treat hypertension. And we believe that is an inappropriate or unfair leap of logic.

JUDGE GREEN: So your argument is basically that the Baldwin reference teaches that a compound is either a xanthine oxidase inhibitor or can be used to treat hypertension, but not do both at the same time?

MR. VAN DYKE: Yes, that, that is one of -- in one of the Patents -- actually in both of them, they specifically point out that the compounds can be used for either xanthine oxidase inhibit -- as a xanthine oxidase inhibitor or as -- to treat hypertension. Ultimately, we don't believe that that's even relevant because they don't realize that it's the uric acid levels that are what's important. So it's that discovery that leads someone to understand that you could use another means of lowering your acid, i.e., Allopurinol, as a

treatment for hypertension. And we have other pending cases, but we have other claims in other Patents to other means of lowering uric acid, not just Allopurinol which is a xanthine oxidase inhibitor. So what it seems that the Examiner's done is said oh, xanthine oxidase inhibitor in this group or specific class of compound, some of them have been shown to have hypertensive activity, so then that must mean any xanthine oxidase inhibitor activity would have antihypertensive activity. And we just think that that's improper, there's really no reason to make that logical leap.

JUDGE LEBOVITZ: Well, I mean reading from the '614 Patent, column 1, I guess it says the use of compounds as oxidase inhibitors or in the treatment of hypertension.

MR. VAN DYKE: Yes.

JUDGE LEBOVITZ: So, I guess your argument is that they didn't recognize that the compounds, which presumably were xanthine oxidase inhibitors, were useful because of that activity to treat hypertension.

MR. VAN DYKE: I believe that is one of our arguments, and I think another interpretation is that there may be some compounds that have one or the other, so --

JUDGE LEBOVITZ: So they could have -- right, compounds could have different activity. And the Declarations, at least one of the ones that you referred to, seem to be saying that this idea that xanthine oxidase inhibitors can be used to treat hypertension is new. You have a couple Declarations which say I'm familiar with Dr. Johnson's work --

MR. VAN DYKE: That's correct.

JUDGE LEBOVITZ: -- and nobody had proposed this before or --

MR. VAN DYKE: That's correct. Maybe I should just maybe clarify that one a little bit.

JUDGE LEBOVITZ: Yes.

MR. VAN DYKE: I think what the Declarations are saying is that no one had ever made the -- known that it was the uric acid that was causative of hypertension, so that was the discovery. And, and upon that discovery, then one skilled in the art would realize aha, now I could use any means of lowering uric acid to treat hypertension.

JUDGE ADAMS: If I could just clarify this idea you just mentioned about the recognition as to whether certain compounds would have a particular activity. Are you talking about just compounds in general or that certain xanthine oxidase inhibitory compounds would have particular activities and that others would have one unique activity, whereas some other xanthine oxidase inhibitors would have multiple activities?

MR. VAN DYKE: Well, I, I may have to bring in my expert on that one, but what I think is correct is that any xanthine oxidase inhibitor is going to inhibit the enzyme xanthine oxidase, and it's that enzyme that ultimately produces uric acid.

JUDGE ADAMS: So in the content -- in the context of the 61 -- I believe it's the 6 -- yes, the '614 Patent, where it says that they're useful as a xanthine oxidase inhibitors or in the treatment of hypertension, your suggestion is that these particular compounds are useful only as xanthine oxidase inhibitors or in the treatment of hypertension, is that your argument?

MR. VAN DYKE: That is one aspect of my argument, yes, and the other aspect would be -- I'm sorry.

JUDGE ADAMS: And you've developed that argument to the point where I need to go back into the record to look for this particular point. It would be helpful if you could direct me to it. Some place in the record where you've developed this concept that particular compounds taught by the '614 Patent are only xanthine oxidase inhibitors to the exclusion of the treatment of hypertension?

MR. VAN DYKE: I think in all fairness that argument has not been developed in the record.

JUDGE ADAMS: That's something that you just brought up today for our, our discussion, is that right?

MR. VAN DYKE: Well, what we argued on the record is that it appears as though -- from the teachings of the -- this Baldwin reference that, that what they're saying is that these compounds can be used for either/or. And --

JUDGE ADAMS: Well, either/or or both, right?

MR. VAN DYKE: They don't -- they never really indicate that they should be used for both.

JUDGE ADAMS: They never really indicate that they shouldn't, that's what you just told me. You've made no argument on the record today to suggest that this reference is speaking only to compounds that inhibit xanthine oxidase or compounds -- or in the alternative, in the exclusive alternative, compounds that treat hypertension. There's nothing on this record to support that specific --

MR. VAN DYKE: No, I apologize. That argument has been made, that, that the proactive teaching of this reference is that it teaches that they can be used either/or, not both.

JUDGE ADAMS: Okay, well, that's your contention, where's your support for your contention other than this one line that says xanthine oxidase inhibitors or in the treatment of hypertension? Whichever you'd prefer, you can do it for this or you can do it for that or you could do it for both, right?

MR. VAN DYKE: Right.

JUDGE LEBOVITZ: I think that that's the point that they're not -- they seem to be saying it's either A or B, they're not saying use the activity to treat hypertension, and I think that may be in Example 9 --

MR. VAN DYKE: That's right.

JUDGE LEBOVITZ: -- they talk about using it to treat hypertensive activity. In Example 10, they talk about it using the xanthine oxidase inhibitor.

MR. VAN DYKE: That, that is correct. And in the '522 Patent, they actually list two different groups.

JUDGE ADAMS: That was interesting, I can't say that that's ever happened before. I was ready to take, you know, duck and roll here.

MR. VAN DYKE: And, and maybe I could just also say I do agree with, with this Judge's interpretation, but I also think that it's important to point out that it ultimately is not relevant because these are -- they don't teach Allopurinol as being able to treat hypertension. They're limited to these specific compounds, and our contention is that there is nothing in

either of these Baldwin Patents to suggest that once you go out and look for other xanthine oxidase inhibitors to treat hypertension and specifically or any other means of lowering uric acid. If that were the case and, you know, I just would like to point out as, as part of this, both of these Patents issued more than 20 years before the filing of this application, and no one ever thought to use Allopurinol as a treatment of hypertension. And if it were obvious from these Baldwin Patents, we would say that it would have been done for an important disease such as hypertension.

JUDGE ADAMS: Anything further?

MR. VAN DYKE: I don't have anything further. I'd be happy to answer any of your questions.

Whereupon, the proceedings, at 9:52 a.m., were concluded.